UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/029,656 | 12/21/2001 | Clive Patience | 329579-3 | 5770 |

7590 07/14/2003

Alan J. Grant, Esq.
c/o Carella, Byrne, Bain, Gilfillan,
Cecchi, Stewart & Olstein
6 Becker Farm Road
Roseland, NJ 07068

| EXAMINER | |
|---|---|
| FOLEY, SHANON A | |
| ART UNIT | PAPER NUMBER |
| 1648 | 8 |

DATE MAILED: 07/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/029,656 | PATIENCE ET AL. | |
| | Examiner | Art Unit | |
| | Shanon Foley | 1648 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) *1-6 and 8-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7 and 52-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

In paper no. 7, applicant added claims 52-55. Claims 1-55 are pending in the application.

### *Election/Restrictions*

Applicant's election with traverse of group VI, SEQ ID NO: 14 in Paper No. 7 is acknowledged. Applicant argues that group VI should be rejoined with the method of group XIV because the recited receptor in the method includes the polypeptide of group VI. Applicant asserts that a search for the polypeptide would necessarily overlap with teachings for using the polypeptide. Applicant states that if the polypeptide is found free of the art then its use in the method of group XIV would also be free of the art. Applicant provisionally elects SEQ ID NO: 13 if group XIV is rejoined with elected group VI.

Applicant's arguments have been fully considered, but are found unpersuasive. According to the MPEP § 806.05(h), patentable distinctness between a product and a process of using the product is demonstrated if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. In the restriction requirement, it was determined that the method of group XIV can be practiced with materially different products of groups I-III and IV-VII. This showing satisfies the first criterion for establishing patentable distinctness between a product and a method of using the product. Therefore, restriction between the product and the method of using the product is proper. Applicant has not presented any argument that different products cannot be used in the method. Therefore applicant's traversal is not persuasive.

Further, a search for the elected product of group VI does not overlap with a search for the method of using the product in group XIV. Each group is separately classified under different statutory classes and a rejoinder of the two groups would require a burdensome search. Further, issues that that may arise during examination of one group may differ.

However, if the elected product is determined to be free of the prior art and applicant still desires a rejoinder of the product with the method of group XIV, applicant's attention is directed to M.P.E.P. §821.04 regarding the restriction of claims to a product and processes of using the product, Rejoinder:

> Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02 (c) and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.
>
> Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either (1) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2), or (2) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined . If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2), even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26 states that "[m]oney paid by actual mistake or in excess will be refunded, but a mere change of purpose after the payment of money...will not entitle a party to demand such a return..." The fees paid under 37 CFR 1.129(b) were not paid by actual mistake nor paid in excess, therefore, applicant would not be entitled to a refund.
>
> In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

> "However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

In accordance with M.P.E.P. §821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-6 and 8-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7. Claims 7 and 52-55 are under consideration.

***Specification***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see page 3, line 4. Applicant is required to delete the hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 52-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to an isolated polypeptide having at least 85% to 98% sequence identity to the polypeptide encoding SEQ ID NO: 14. The claims do not require that the protein possesses any particular distinguishing feature, biologic activity, or conserved structure. Therefore, the claims are drawn to a genus of polypeptides that are defined only by sequence identity.

The claims also encompass immunogenic fragments of polypeptides that have 85% to 98% sequence identity to SEQ ID NO: 14. An immunogenic fragment is defined in the specification on page 13, lines 19-22 as reacting with an antibody that is specific for the polypeptide or eliciting the production of polypeptide-specific antibodies. If the polypeptide comprises a 2% to 15% difference in sequence identity from SEQ ID NO: 14, the polypeptide is capable of eliciting antibodies and reacting with antibodies that do not react with SEQ ID NO: 14. SEQ ID NO: 14 comprises 448 amino acids. A 2% variation of 448 residues is approximately 10 amino acids and a 15% difference in 448 residues is approximately 75 amino

acids. Cruse et al. (Illustrated Dictionary of Immunology. Boca Raton: CRC Press, Inc.; 1995. pages 102-103) defines an epitope as an antigenic determinant that must be at least 1 kD to elicit an antibody response. 1 kD corresponds to approximately 9 amino acids (one amino acid equals approximately 110 daltons). Therefore, immunogenic fragments that encompass sequences from polypeptides that differ in sequence identity by 2% to 15% are capable of eliciting antibodies that are not elicited by SEQ ID NO: 14. The claims encompass immunogenic fragments with no defined structure or function and the specification does not reasonably convey possession of these undefined fragments.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at

page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the genus of polypeptides or immunogenic fragments thereof, given that the specification only describes SEQ ID NO: 14.

Therefore, only isolated polypeptides comprising the amino acid sequence set forth in SEQ ID NO: 14, but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 7 is rejected under 35 U.S.C. 102(a) as being anticipated by a sequence alignment of SEQ ID NO: 14 with SPTREMBL_21 database accession number Q9NWF4 of Isogai et al. submitted October 1, 2000.

The claim is drawn to immunogenic fragments of a polypeptide comprising SEQ ID NO: 14.

Isogai et al. teach a polypeptide sequence that is 99.8% sequence identity to SEQ ID NO: 14, see the sequence alignment provided. There is only a single residue difference between the sequence of Isogai et al. and instant SEQ ID NO: 14. The polypeptide of Isogai et al. would

inherently include epitopes in common with SEQ ID NO: 14 by virtue of the 99.8% identity. Cruse et al. *supra* defines an epitope as an antigenic determinant that must be at least 1 kD to elicit an antibody response. 1 kD corresponds to approximately 9 amino acids (one amino acid equals approximately 110 daltons). Therefore, the polypeptide of Isogai et al. inherently comprises the immunogenic fragments of SEQ ID NO: 14.

Claims 52-55 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by a sequence alignment of SEQ ID NO: 14 with SPTREMBL_21 database accession number Q9NWF4 of Isogai et al. submitted October 1, 2000.

The claims are drawn to an isolated polypeptide comprising an amino acid sequence having at least 85% to 98% sequence identity to SEQ ID NO: 14.

The sequence of Isogai et al. has 99.8% sequence identity to instant SEQ ID NO: 14, see the sequence alignment provided. Therefore, the polypeptide sequence of Isogai et al. clearly anticipate the limitations of the claims.

Claims 52-55 are rejected under 35 U.S.C. 102(b) as anticipated by Shoyab et al. (US 4,714,683).

The claims are drawn to immunogenic fragments of isolated polypeptides comprising an amino acid sequence having 85% to 98% sequence identity to SEQ ID NO: 14.

The instant disclosure does not structurally define the length of the claimed immunogenic fragments of the polypeptides comprising the recited sequence identities. Therefore, the immunogenic fragments may be of any length and constitute any amino acid sequence within the polypeptide comprising the recited sequence identities. As discussed above, a polypeptide that has a sequence identity of 98% to SEQ ID NO: 14 comprises approximately 10 residues that are

different from SEQ ID NO: 14 and a polypeptide that has a sequence identity of 85% to SEQ ID NO: 14 comprises approximately 75 residues that are different from SEQ ID NO: 14. The instant immunogenic fragments may only comprise the 10 to 75 amino acid residues derived from the portion of the polypeptide that differs in sequence with SEQ ID NO: 14 between 2% and 15%.

Shoyab et al. anticipate a polypeptide sequence comprising at least 15 amino acids and not more than 125 amino acids, see claim 9. This range includes a polypeptide of 75 amino acids. Since the instant immunogenic fragments are not defined by any particular structure or length, the polypeptide sequence of Shoyab et al. anticipate the instant immunogenic fragments with no defined structure.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

A sequence alignment of SEQ ID NO: 14 with Geneseq_101002 database accession number AAB92492 of Ota et al. submitted June 26, 2001 reveals a 99.8% sequence identity to SEQ ID NO: 14, see the sequence alignment provided. The date of entry into the sequence database, June 26, 2001, does not constitute prior art. However, the European patent, EP1074617-A2, which claims SEQ ID NO: 10589 in claim 8, has a relevant prior art date of February 7, 2001. However, this reference is not being relied upon as prior art because the patent is 2537 pages and the residue difference, which occurs at position number 296, is the exact same difference in the sequence of Isogai et al. in the prior art rejection discussed above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley
July 13, 2003